

Test and Treat Guidance

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*One of the Four Key
Components to
eliminate HIV
Transmission and
Reduce HIV-related
Deaths*





Guidance on Florida's Test and Treat Program for Antiretroviral (ART) Initiation

HIV/AIDS Section

HIV Program Component 03

INTRODUCTION

Florida has a plan with Four Key Components to eliminate HIV Transmission and Reduce HIV-related Deaths; Test and Treat (T&T) is one of the four key components. T&T is a clinical program providing immediate linkage to HIV care and initiation of ART at the time of HIV diagnosis and/or at the time of returning to care after a gap in services. The program benefits the patient's health and the community by providing initial ART while working through the issues of eligibility and linkage to ongoing HIV care.

PURPOSE OF THIS GUIDANCE

- To provide the medical and public health rationale for T&T.
- To serve as a practical guide for the medical, counseling and care planning components of the statewide program.

RATIONALE FOR TEST AND TREAT PROGRAM FOR ART INITIATION

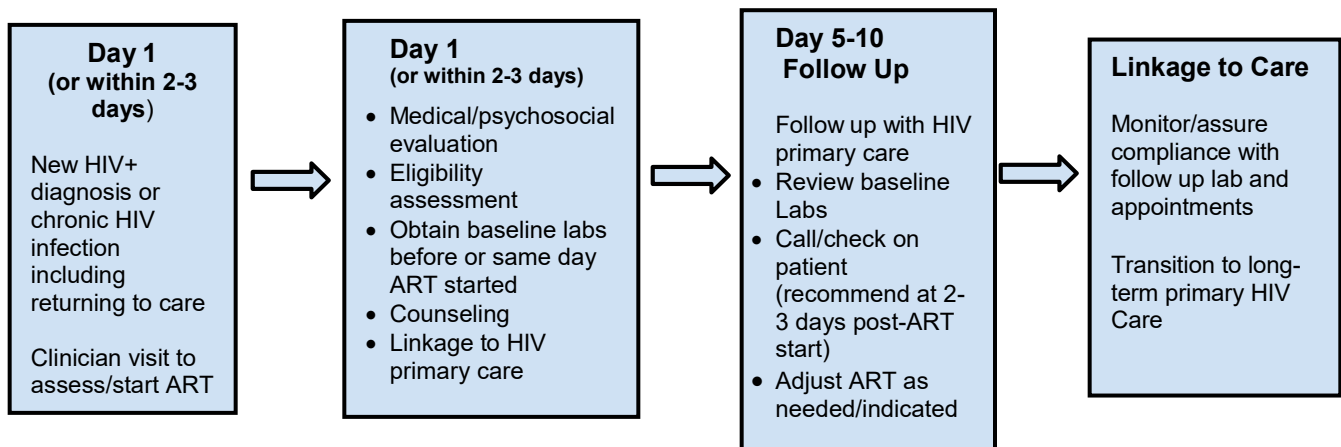
The HIV Department of Health and Human Services (DHHS) Guidelines currently recommend universal ART for all people living with HIV regardless of CD4 count as soon as possible. Increasing data show a medical benefit to the patient when immediate ART is initiated, particularly during acute/early HIV infection. There is also a community-level public health benefit of reduced HIV transmission. Many patients report that the decision to start ART and the rapid achievement of viral suppression provides them with the first experience of empowerment to live successfully with HIV.

ELIGIBILITY FOR TEST AND TREAT

Newly diagnosed HIV patients defined as:

- Acute Infection: antibody (-)/RNA (+).
- Recent Infection: antibody (+) with last documented antibody (-) within prior 6 months.
- Chronic Infection: antibody positive with no prior HIV test result or last documented antibody (-) > 6 months ago (inclusive of patients lost to follow up and returning to care).

No available clinical trial to which the patient can be enrolled, or patient declines clinical trial enrollment.





Note: The goal of the T&T Program is for a newly diagnosed patient or a patient newly re-engaged into HIV care to see an HIV clinician, be offered ART, receive counseling and agree on a sustainable care plan on the day of diagnosis/re-engagement, or within 2 to 3 days if same-day initiation is not possible.

TEST AND TREAT PROGRAM CONSISTS OF 3 BASIC STEPS FOLLOWING CONFIRMATION OF HIV DIAGNOSIS:

1. Communication of a new diagnosis from the testing site to a T&T team member (a single point of contact—such as a dedicated staff person(s) with a cell phone/pager/other).
2. The initial T&T visit with ART initiation or, if ART cannot be provided, immediate navigation to a clinic where ART is available.
3. Expedited linkage to ongoing HIV primary care (which may continue at T&T site if available, or at another HIV primary care site appropriate for and acceptable to the patient and/or required by insured status). Some details of the process will differ depending on where the patient is diagnosed with HIV infection and where he or she can receive immediate ART.

STEP ONE: TEST AND TREAT – PATIENT REFERRAL

- A. Patients who test HIV positive at a testing site and receive post-test counseling can be referred to a T&T clinic site. The T&T team is contacted during hours of operation and informed of the HIV-positive test result. Determination of whether the diagnosis is a new chronic diagnosis or whether it is likely to be an acute infection is then made.
- B. Upon arrival, the patient is welcomed by a clinical team member and then will see a clinician for assessment and determination for starting ART. After seeing the clinician, there will be additional post-test counseling and education, assessment of eligibility and insurance/coverage and linkage to ongoing care planning. The T&T team members will vary by County Health Department (CHD) based on available staffing/resources. The team may include a nurse, case manager, Disease Intervention Specialist (DIS), eligibility staff, clinician and other staff who will assist with linking the patient to care services. If not already done, counseling for Partner Services (PS) should occur during this visit.
- C. Advice on making T&T work is for the receiving clinic to designate a “TEST AND TREAT DESIGNEE of the DAY,” a team member who will be the single point of contact for receiving the referral and will organize the rapid response. This person may be a case manager, clinic designee or other staff who will call upon the personnel needed to treat the patient that day (medical evaluation, counseling on starting ART, phlebotomy, eligibility and benefits counseling, navigation, scheduling and notification of PS).

Instead of performing the majority of the counseling up front before therapy starts, counseling begins after diagnosis and continues after a patient is started on treatment. With this approach, all standard individualized counseling components are covered, initiation of ART is not delayed and there is an opportunity to continue counseling while the patient is initiating therapy.

- D. A sustainable, long-term care plan should be established. Successful outcomes in HIV depend not only on the rapid initiation of therapy but also upon the establishment of a sustainable HIV-care plan. Based on the initial assessment of potential barriers for successful linkage to care, a plan is put in place with the HIV staff/case manager to address both immediate and long-term barriers. This may include emergency housing, immediate access to insurance and drug benefits, expedited access to mental health services or residential drug treatment programs, counseling and referrals to deal with other concerns.
- E. Based on the identification of barriers to linkage and retention in care, a contingency plan is identified for potential problems such as missed appointments, missed doses of ART and inability to fill medications at the pharmacy. Patients are given clear guidance on how to get help, support and remain connected to the clinic.

STEP TWO: INITIAL TEST AND TREAT CLINIC VISIT

A. Medical Evaluation:

HIV history: An HIV risk/prevention history will be taken and recorded, including:

- Date of last negative HIV test and prior HIV test(s)/result(s)
- PrEP use
- PEP use
- Sexual practices and serostatus of partners, if known

B. Psychosocial Evaluation:

- Substance abuse/mental health assessment
- Housing/food
- Readiness to start ART

C. Medical history/targeted exam:

A quick medical history/targeted exam will be taken, particularly since patients will be started on ART before most laboratory test results have returned:

- Co-morbidities (especially renal/liver problems)
- Medications
- Drug allergies
- Review of systems (to alert for the presence of opportunistic infections (OIs) or HIV-seroconversion symptoms) and targeted clinical exam for HIV-related signs (for example, thrush, lymphadenopathy and skin lesions)

D. Counseling on the risks and benefits of immediate ART:

A full discussion occurs with the patient regarding the risks and benefits of immediate ART. The role of viral load monitoring will also be included in this discussion to introduce the concept of ongoing monitoring and therapy goals. The patient is informed about the possibility of developing an immune-reconstitution syndrome. The patient is also reminded about the importance of being in close contact with the health system during early months of treatment should any complications arise related to medication or HIV disease. Emphasis is placed upon listening to patient concerns and conveying to the patient that he or she will likely have additional questions through this process and the team is available to address these.

E. Initiation of immediate ART:

The provider reviews the patient's plan for long-term ART and follow-up care.

If there is no clear contraindication and the patient does not decline, the provider offers, selects (in consultation with the patient) and prescribes/dispenses immediate ART.

Selection of ART: The selection of a particular ART regimen for an individual patient will depend upon the patient's preferences, co-morbidities, potential drug interactions and drug allergy history.

Because most patients will be initiated on ART before the results of laboratory tests are available (in particular the HIV viral load, genotype, creatinine, liver function tests and HLA-B*5701 test for predisposition to abacavir hypersensitivity), the following are recommended T&T ART regimens.

The T&T regimens outlined below have been purchased and are available for CHDs from Central Pharmacy in 30-day starter packs. ***The attached CHD order form must be completed to request the ART regimens to be shipped from Central Pharmacy to your CHD site.***

RECOMMENDED 30-DAY ART REGIMENS FOR TEST AND TREAT:

- Dolutegravir 50 mg once daily (Tivicay®) + tenofovir alafenamide/emtricitabine (Descovy®) one (1) tab once daily or
- Darunavir/cobicistat (Prezcobix®) once daily + tenofovir alafenamide/emtricitabine (Descovy®) one (1) tab once daily or
- Bicitgravir + tenofovir alafenamide/ emtricitabine (Biktarvy®) one (1) tablet taken once daily with or without food

In cases of high level known resistance, at the provider's discretion, combinations of PI/INSTI plus or minus NRTI may be dispensed

F. Laboratory studies: See AIDSinfo Laboratory Testing for initial assessment and monitoring of HIV-infected patients on ART at

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/3/tests-for-initial-assessment-and-follow-up>

G. Prescribing and/or Dispensing Initial ART

Medication Available On-Site

- Once an ART regimen has been selected, the clinician/health care team dispenses a 30-day supply of medication. The goal is to provide sufficient ART until the patient's AIDS Drugs Assistance Program (ADAP)/insurance/coverage is able to supply continuing medication.
- The patient is encouraged to take the first dose of ART during the initial visit.
- CHDs must maintain medication logs showing drug was dispensed to qualified patients for the T&T Program.
- **NOTE:** If an additional 30-day supply of ART medication is required (additional 30-day starter pack), documentation should be provided as to why there was a delay over 30 days for the patient's medication coverage.



- DHHS HIV/AIDS Treatment Guidelines may be accessed at <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0>

STEP THREE: LINKAGE TO CARE/FOLLOW UP

Day one to three days after ART Initiation: A member of the health care team assesses/provides medical/psychosocial support, arranges for eligibility assessment and obtaining baseline labs and/or referring for initial lab work. Provide resources/support for the patient to coordinate filling their ART prescription. Any medical symptoms or questions are conveyed to the provider for the appropriate follow up.

Day 5 through 10: The patient has an appointment with the medical provider to follow up on clinical care and laboratory tests. At that visit, lab results are reviewed with the patient. An assessment is done for HIV and any medication side effects. Treatment may be adjusted as appropriate. If the CHD or clinic that initiated T&T will be following the patient for their ongoing HIV care, appointments can be made accordingly. If the patient will be following up with another HIV medical provider, the case manager should assist with arranging a clinic appointment for follow up on days 5 through 10. Care resumes with the provider for routine primary HIV care with an emphasis on retention in long-term care.

Ongoing: Access to a medical case manager is provided during this time period and over the next three or more months to continue with the stabilization plan, to provide ongoing support and education for coping with stigma, partners/family/friends' disclosure and other barriers.

Appointment reminders are made and immediate follow up is completed for any missed appointment(s), including outreach and home visits.

For medication adherence, the Care4Today website is one resource you may share with patients including a mobile technology application for use. The link is <https://www.care4today.com/mhm>.

For patients at risk for poor retention in care, make referrals to case managers and provide overlapping support until the patient has established a relationship with the case manager.

Test and Treat Intervention Components

- Facilitation of same day/next day appointments
- Flexible scheduling for providers (on call/back up)
- ART regimens pre-approved for use prior to genotyping or lab testing
- Available onsite ART
- Accelerated process for Ryan White eligibility/health insurance coverage
- Recommendation for first dose to be taken observed in the clinic

Data Outcomes

Time to specific milestones: The T&T program tracks dates at which each patient achieves specific care milestones. This allows analysis of the time delays that occur at each step of the disclosure, referral, linkage and engagement process. Dates for the following milestones are collected (they need not occur in order):

- First positive diagnostic test



- Test result disclosure
- Last negative HIV test result
- Clinic contact/referral
- First clinic visit
- First clinic medical provider visit
- First ART prescription date (after diagnosis of infection)
- First viral load suppression <200 cells/mm³
- Linkage to primary HIV care within 30 days and documentation patient maintained in care, through data collection over 12-month period
- Engagement in care at 12 months
- Viral suppression <200 cells/mm³ and $<$ lowest limit of detection defined by lab, through data collection over 12-month period

Technical Assistance, Training and Resources

Technical assistance and training may be requested by calling the HIV/AIDS Section Medical Team at (850) 901-6676 or email Roselyn.Jasmin@flhealth.gov

Test and Treat ART medications: Central Office in Tallahassee has arranged a stable supply of starter packs available to the CHDs through Central Pharmacy. See the T&T order form to place an order for the T&T regimens from Central Pharmacy.

Training is available through the Southeast AIDS Education and Training Center (SE AETC) <http://aidsetc.org/directory/regional/southeast-aids-education-and-training-center> through the following SE AETC Florida Partner Sites:

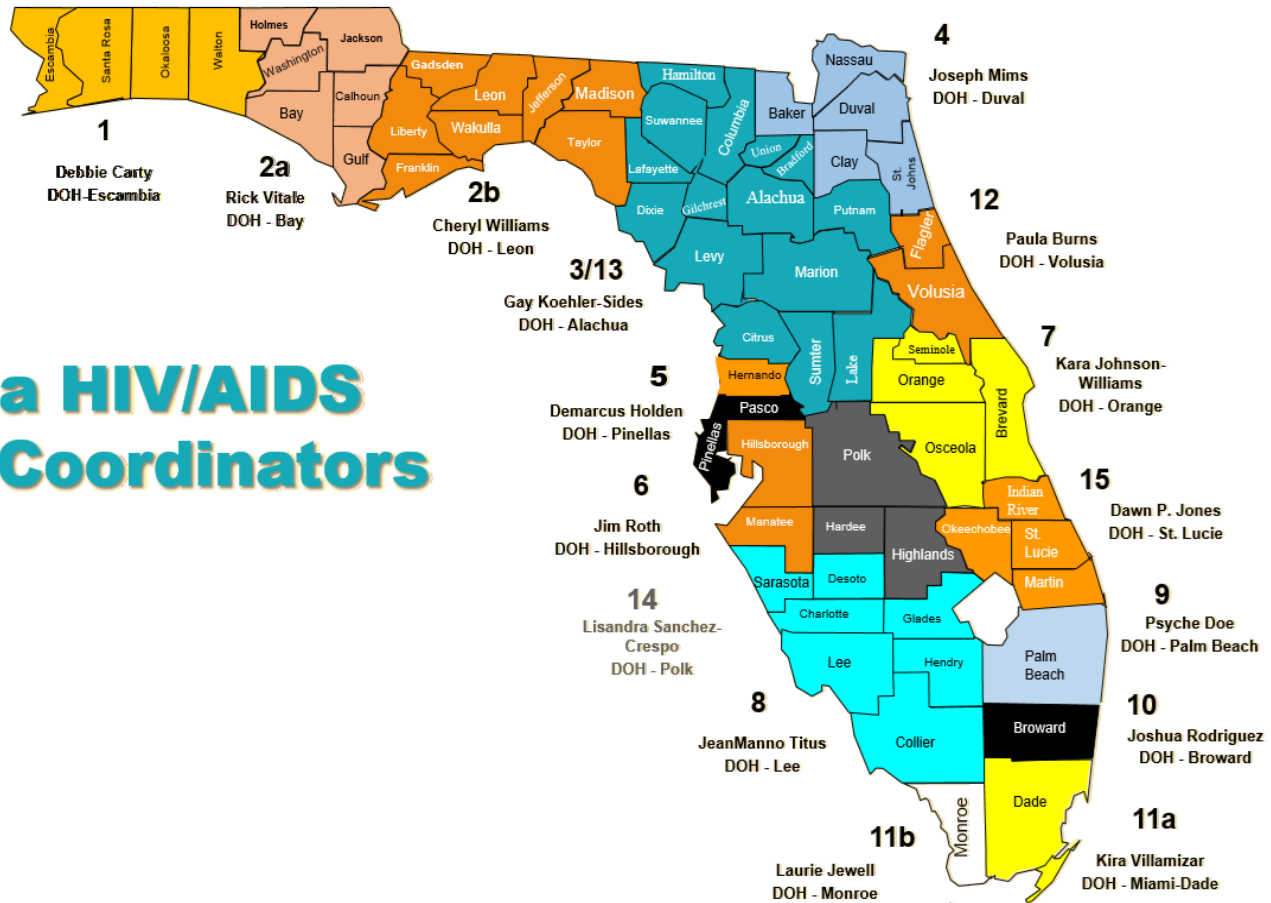
- North Florida AETC: call (352) 273-7845 or <http://aetc.medicine.ufl.edu/>
- South Florida AETC: Martia West, MHP, Administrator (305) 582-2233 or Lissette Lahoz, MPH, Program Manager (610) 248-2776

Phone consultation on HIV/AIDS management is available to clinicians at the Clinician Consultation Center (CCC) at (800) 933-9413, Monday–Friday, 9:00 a.m.–8:00 p.m. EST. The website link to CCC is <http://nccc.ucsf.edu/clinician-consultation/hiv-aids-management/>



For the Florida Department of Health HIV/AIDS Program Coordinators statewide contact information, please call Debbie Norberto at (850) 901-6681 or email Debbie.Norberto@flhealth.gov

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